

## State Stem Cell & Gene Therapy Agency Sets up Support Program to Help Patients Participate in Clinical Trials

Posted: September 29, 2022

For many patients battling deadly diseases, getting access to a clinical trial can be life-saving, but it can also be very challenging. Today the governing Board of the California Institute for Regenerative Medicine (CIRM) approved a concept plan to make it financially and logistically easier for patients to take part in CIRM-funded clinical trials.

The plan will create a Patient Support Program (PSP) to provide support to California patients being evaluated or enrolled in CIRM-supported clinical trials, with a particular emphasis on helping underserved populations.

"Helping scientists develop stem cell and gene therapies is just part of what we do at CIRM. If those clinical trials and resulting therapies are not accessible to the people of California, who are making all this possible, then we have not fulfilled our mission," says Maria T. Millan, M.D., President and CEO of CIRM.

The Patient Support Plan will offer a range of services including:

- Clinical trial navigation, directing patients to appropriate CIRM-supported clinical trials.
- Logistical support for patients being evaluated or enrolled in clinical trials.
- Financial support for under resourced and underserved populations in CIRM-supported clinical trials, including the CIRM Patient Assistance Fund (PAF). This support includes transportation/travel expenses, such as gasoline, tolls, parking, airfare, taxi, train, lodging, and meals during travel.
- Providing nurse navigator support for the psychosocial, emotional, and practical needs of patients and their families.

The funds for the PSP are set aside under Proposition 14, the voter-approved initiative that re-funded CIRM in 2020. Under Prop 14 CIRM money that CIRM grantees earn from licensing, inventions or technologies is to be spent "offsetting the costs of providing treatments and cures arising from institute-funded research to California patients who have insufficient means to purchase such treatment or cure, including the reimbursement of patient-qualified costs for research participants."

Currently, the CIRM Licensing Revenues and Royalties Fund has a balance of \$15.6 million derived from royalty payments.

"The patient support program and financial resources will not only help patients in need, it will also help increase the likelihood that these clinical trials will succeed," says Sean Turbeville, Ph.D., Vice President of Medical Affairs and Policy at CIRM. "We know cell and gene therapies can be particularly challenging for patients and their families. The financial challenges, the long-distance traveling, extended evaluation, and family commitments can make it difficult to enroll and retain patients. The aim of the PSP is to change that."

The overall objective of this funding opportunity is to establish a statewide program that, over five years, is expected to support hundreds of patients in need as they participate in the growing number of CIRM-supported clinical trials. The program is expected to cost between \$300,000 to \$500,000 a year. That money will come from the Medical Affairs budget and not out of the patient assistance fund.

The first phase of the program will identify an organization, through a competitive process, that has the expertise to provide patient support services including:

- Maintaining a call and support center.
- Assessing patient eligibility for financial assistance.
- Reporting to CIRM on patients needs and center performance

You can find more information about the Patient Support Program on our website [here](#) and [here](#).

At CIRM, we never forget that we were created by the people of California to accelerate stem cell treatments to patients with unmet medical needs, and act with a sense of urgency to succeed in that mission.

To meet this challenge, our team of highly trained and experienced professionals actively partners with both academia and industry in a hands-on, entrepreneurial environment to fast track the development of today's most promising stem cell technologies.

With \$5.5 billion in funding and more than 150 active stem cell programs in our portfolio, CIRM is one of the world's largest institutions dedicated to helping people by bringing the future of cellular medicine closer to reality.

For more information go to [www.cirm.ca.gov](http://www.cirm.ca.gov)

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